DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 2 0 2010

Food and Drug Administration
Rockville MD 20857

Re: IXIARO
Docket No.: FDA-2009-E-0416

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 6,309,650, filed by Chiel Jedang Corp & Walter Reed Army Institute of Research, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for IXIARO (Japanese Encephalitis Virus, Vaccine Inactivated, Adsorbed), the human biological product claimed by the patent.

The total length of the regulatory review period for IXIARO is 3,461 days. Of this time, 2,994 days occurred during the testing phase and 467 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: October 10, 1999.

   The applicant claims October 9, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was October 10, 1999, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: December 20, 2007.

   FDA has verified the applicant's claim that the biologics license application (BLA) for IXIARO (BLA B125280/0) was initially submitted on December 20, 2007.

3. The date the application was approved: March 30, 2009.

   FDA has verified the applicant's claim that BLA B125280/0 was approved on March 30, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: William T. Christiansen, Ph.D.
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